

REMARKS

I. Status of the claims and Support for Amendment

Claim 42 is amended and new claims 42–44 are added.

Claims 31 and 37–44 are currently pending.

Claims 38–40 are currently withdrawn from examination.

Support for the Amendments to claim 41 is found in the specification at pages 17, 37, and 40.

Support for new claims 42–44 is found in claim 31 as originally filed and in the specification at pages 17, 30, 31, and 37–40.

II. Rejection under 35 U.S.C. § 112

A. Claims 31, 37, and 41 are rejected under 35 U.S.C. § 112, first paragraph for allegedly containing new matter for their use of the term “*specifically hybridizes*”. Applicant responds as follows.

While Applicant does not concede that the term “specifically hybridizes” constitutes new matter, this term has, nevertheless been removed from the pending claims. Accordingly, this rejection is moot and may now properly be withdrawn.

B. Claims 31 and 41 are rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter that was not described in the specification. Specifically, the rejection recites that “[t]he instant claims are drawn to probes that hybridize to the genomic RNA of a deposited retrovirus under undefined conditions. Hence, the specification provides insufficient written description to support the genus encompassed by the claim”. Applicant respectfully traverses.

As currently amended claim 41 provides for stringent conditions. Further, stringent conditions are specifically defined in the claims as being as stringent as “*hybridization in 3X SSC, 0.5% milk powder, 1% SDS, 10% dextran sulfate, and 50% formamide (volume/volume) at 42 °C for 18*

hours followed by two 30 minute washes in 0.1 X SSC and 0.1% SDS at 65 °C". This limitation clearly conveys to one skilled in the art how stringent the conditions must be to fall within the claim. Applicant notes that those skilled in the art are aware of manifold hybridization conditions and would fully appreciate that the claimed process simply requires that the probe hybridize under conditions that are as stringent as those recited. Moreover, the skilled artisan would appreciate that the claimed process is not limited to those specific hybridization/wash conditions recited in the claims. The claims also cover use of hybridization conditions that provide similar stringency to the recited conditions. In other words the recited conditions are exemplary.

C. Claims 31, 37, and 41 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled. The rejection recites, in part, that:

[t]he specification fails to specifically define what parameters constitute "stringent conditions". Therefore, said term is not limiting. As disclosed above, the specification does not teach how to make any polynucleotides that specifically hybridize to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Clearly, since the specification has not taught how to make/use said polynucleotides, the specification has not enabled the instant claims that require DNA probes that specifically hybridize to the genomic RNA of the HIV retrovirus.

Applicant respectfully traverses.

Applicant disagrees with the generalization that the specification does not define "stringent conditions". This term and an example thereof are explicitly recited at page 17, lines 16–24 of the specification. Further, as noted in part "B.", the currently pending claims no longer recited the term "specifically hybridize". Moreover, the hybridization parameters exemplifying "stringent conditions" are now recited in the claims. In view of these facts, Applicant contends that the pending claims are fully enabled. In view of the biological deposit, one skilled in the art would have no difficulty making and using probes, that hybridize with the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301, under the recited conditions, without undue experimentation.

Accordingly, Applicant believes the rejections of claims 31, 37, and 41 for lack of enablement has been overcome and may now properly be withdrawn.

D. Claims 31, 37, and 41 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for the use of the phrase “stringent hybridization conditions.” As noted above, the claims are currently amended to recite parameters that are exemplary of the phrase “stringent hybridization conditions”. One skilled in the art would now clearly understand the phrase “stringent hybridization conditions” to mean carrying out hybridization under conditions effective to provide stringency comparable with the stringency provided using the parameters recited in the claims. Further, the skilled artisan would understand that this might mean using the conditions recited or other conditions that provide similar stringency. Accordingly, Applicant believes that this rejection has been overcome and may now properly be withdrawn.

III. Rejection under 35 U.S.C. § 102

Claims 31 and 41 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Montagnier *et al.* (WO 86/02383). The rejection recites, in pertinent part, that “the terms ‘specifically hybridizes’ and ‘stringent conditions’ have not been explicitly defined in the specification []. Therefore, said terms are not limiting.” Applicant respectfully traverses.

Chapter 2100 of the *MPEP* states that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987).” (*MPEP* § 2131).

As described above, the claims no longer recite the phrase “specifically hybridizes”. Further, the claims now recite specific conditions that are exemplary of the phrase stringent conditions. In view of these amendments the claims now require use of a probe that is capable of hybridizing with “the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures

(ECACC) under No. V88060301" under the stringent hybridization/wash conditions recited in claim 41. Montagnier *et al.* does not describe either expressly or inherently a probe as required by the current claims. Accordingly, Montagnier *et al.* does not anticipate the currently pending claims. Therefore, the rejection under 35 U.S.C. § 102(b) may now properly be withdrawn.

IV. Conclusions

In view of the foregoing Amendments and Remarks, Applicant believes that all rejections of the pending claims have been addressed and overcome. Further, it is Applicant's belief that the newly added claims meet all requirements for patentability. Accordingly, Applicant respectfully requests favorable reconsideration of the case and issuance of a Notice of Allowance therefor.

In an effort to facilitate progression to grant, the Examiner is invited to contact the undersigned attorney at (713) 787-1589 with any questions, comments, or suggestions relating to the referenced patent application.

Respectfully submitted,



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